

§ 159.152

40 CFR Ch. I (7–1–10 Edition)

159.184 Toxic or adverse effect incident reports.

159.188 Failure of performance information.

159.195 Reporting of other information.

AUTHORITY: 7 U.S.C. 136–136y.

SOURCE: 63 FR 49388, Sept. 19, 1997, unless otherwise noted.

Subparts A–C [Reserved]

Subpart D—Reporting Requirements for Risk/Benefit Information

§ 159.152 What the law requires of registrants.

(a) Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) states: “If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, he shall submit such information to the Administrator.”

(b) Section 152.50(f)(3) of this chapter requires applicants to submit, as part of an application for registration, any factual information of which he is aware regarding unreasonable adverse effects of the pesticide on humans or the environment, which would be required to be reported under section 6(a)(2) if the product were registered.

(c) Compliance with this part will satisfy a registrant’s obligations to submit additional information pursuant to section 6(a)(2) and will satisfy an applicant’s obligation to submit additional information pursuant to § 152.50(f)(3) of this chapter.

§ 159.153 Definitions.

(a) For the purposes of reporting information pursuant to FIFRA section 6(a)(2), the definitions set forth in FIFRA section 2 and in 40 CFR part 152 apply to this part unless superseded by a definition in paragraph (b) of this section.

(b) For purposes of reporting information pursuant to FIFRA section 6(a)(2), the following definitions apply only to this subpart:

Established level means a tolerance, temporary tolerance, food additive regulation, action level, or other limita-

tion on pesticide residues imposed by law, regulation, or other authority.

Formal Review means Special Review, Rebuttable Presumption Against Registration (RPAR), FIFRA section 6(c) suspension proceeding, or FIFRA section 6(b) cancellation proceeding, whether completed or not.

Hospitalization means admission for treatment to a hospital, clinic or other health care facility. Treatment as an out-patient is not considered to be hospitalization.

Maximum contaminant level (MCL) means the maximum permissible level, established by EPA, for a contaminant in water which is delivered to any user of a public water system.

Non-target organism means any organism for which pesticidal control was either not intended or not legally permitted by application of a pesticide.

Pesticide means a pesticide product which is or was registered by EPA, and each active ingredient, inert ingredient, impurity, metabolite, contaminant or degradate contained in, or derived from, such pesticide product.

Qualified expert means one who, by virtue of his or her knowledge, skill, experience, training, or education, could be qualified by a court as an expert to testify on issues related to the subject matter on which he or she renders a conclusion or opinion. Under Rule 702 of the Federal Rules of Evidence, a person may be qualified as an expert on a particular matter by virtue of “knowledge, skill, experience, training, or education.” In general, EPA wants registrants to report information when a person has relevant expert credentials, e.g., a medical doctor giving a medical opinion, a plant pathologist giving an opinion on plant pathology, etc.

Registrant includes any person who holds, or ever held, a registration for a pesticide product issued under FIFRA section 3 or 24(c).

Similar species means two or more species belonging to the same general taxonomic groups: The general taxonomic groups for purposes of this requirement are: mammals, birds, reptiles, amphibians, fish, aquatic invertebrates, insects, arachnids, aquatic plants (including macrophyte, floating,